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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,046	12/05/2003	Alexander M. Harmon	022956-0235	9312

21125 7590 03/25/2009

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EXAMINER	
STEWART, ALVIN J	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
03/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/729,046	HARMON ET AL.	
	Examiner	Art Unit	
	Alvin J. Stewart	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,10,12-25,27 and 28* is/are pending in the application.

4a) Of the above claim(s) *7,14-19,21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10,12,13,20,23-25,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/05/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 9, 10, 12, 13, 20, 23-25, 27 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Binette et al US Patent Pub. 2004/0078090 A1.

The applied reference has a common inventor (Julia Hwang) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Binette et al discloses a biocompatible tissue implant comprising a naturally occurring biocompatible tissue slice having a geometry, the tissue slice including an effective amount of viable cells and further being dimensioned so that the cells can migrate out of the tissue disclosing the tissue strip and the sutures. See paragraph 12, 13, 34, 35, 36, 52.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 9, 10, 12, 13, 20, 23-25, 27 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/374,772. Although the conflicting claims are not identical, they are not patentably distinct from each other because both cases disclose a biocompatible tissue implant comprising a naturally occurring biocompatible tissue slice having a geometry, the tissue slice including an effective amount of viable cells and further being dimensioned so that the cells can migrate out of the tissue disclosing the tissue strip and the sutures.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

Claims 1-6, 9, 12-13, 20, 23-25 and 27-28 are rejected under 35 U.S.C. 103(a) as obvious over Albrecht (Closure of Osteo. Lesions using Chondral Fragments and Fibrin Adhesive)(NPL document provided by the applicant) in view of Badylak et al US Patent 6,485,723.

Albrecht discloses a biocompatible implant comprising a biocompatible scaffold and at least one tissue fragment that is associated with at least a portion of the scaffold, wherein the tissue fragment includes an effective amount of viable cells that can migrate out of the tissue fragment and populate the scaffold. Additionally, Albrecht et al teach a biocompatible implant comprising collagen foam or fibrin adhesive, or a combination of both along with fine minced cartilage tissue (including the viable cells contained therein) and an additional biological component such as thrombin enzyme used in the closure of osteochondral lesions in experimental animals (see Albrecht et al, summary, page 213, and materials and methods, page 214, in particular). Albrecht et al teach an implant comprising a plastic plug of fibrin adhesive with cartilage tissue fragments (such as autogenic tissue) with or without a natural polymer such as porous collagen foam (commercial preparation; Tachotop, Hormonchemie, Munich; see Albrecht et al, page 214, *materials & methods*, in particular) and additional biological component such as thrombin enzyme. Although, the prior art reference does not explicitly disclose the limitations of additional biological components (as recited specifically in the instant claims 19 and 20), the minced cartilage tissue used for the surgical repair along with fibrin glue and/or collagen foam inherently contains the growth factors, peptides, matrix proteins, platelets, etc., and therefore, anticipates the claimed invention. However, Albrecht does not disclose an isolated biological tissue slice harvested from healthy tissue.

Badylak et al teaches a biocompatible tissue implant comprising a naturally occurring biocompatible tissue slice having a geometry, the tissue slice including an effective amount of viable cells (see col. 2, lines 15-19; col. 3, lines 1-5; col. 3, lines 18-20; col. 3, lines 30-61; col. 4,

lines 1-14) and further being dimensioned so that the cells can migrate out of the tissue disclosing the tissue strip and the sutures.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric scaffold of the Albrecht reference with the SIS of the Badylak et al reference in order to increase the biocompatibility of the implant.

NOTE: claim 10 has not been examined because claim 9 is referring to a Markush claim and the Examiner only select one element from the group. The elected group is a suture.

Regarding claim 13, Badylak et al discloses the claimed invention except for particles sizes having a range of about 0.1 mm^3 to 2 mm^3. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the particle size, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/
Primary Examiner, Art Unit 3774

03/18/09.